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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,004	03/06/2000	John Paul Maye	046436-5016	7731
21874	7590	03/08/2007	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			STULII, VERA	
		ART UNIT	PAPER NUMBER	
		1761		
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	03/08/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/520,004	MAYE ET AL.	
	Examiner	Art Unit	
	Vera Stulii	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 February 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At various points in claim 2, the recited limitations appear:

- "aqueous process medium"
- "hop acid"
- "aqueous alkaline medium"
- "aqueous alkaline hop acid solution"
- "yeast hop acid mixture"

To this point, the method of step (b) of claim 2 recites combining the aqueous alkaline hop acid solution with yeast to form a yeast hop acid mixture, and introducing the yeast hop acid mixture into the aqueous process medium", while step (c) recites the step of "continuously adding an effective amount of the aqueous alkaline hop acid solution ... to the aqueous process medium". Applicant's claims are confusing and disjointed, where terms such as "aqueous process medium" are an apparent attempt to indicate the same material at different points in the method, for which multiple and inconsistent designations have been assigned. Applicant is encouraged to amend the claims to clearly and distinctly point out that which applicant regards as the invention, and to

maintain consistency and continuity throughout the claims, both with regard to the independent claim(s), as well as all dependent claims. It is noted that the current status of the claims renders them difficult to compare against the prior art.

Claim 2 recites the limitation "the aqueous process medium" in step b). There is insufficient antecedent basis for this limitation in the claim. Claim 2 is indefinite for the recitation of the term "controlling". It is not clear as to what "controlling" means: inhibiting the growth of micro-organisms, or promoting the growth of micro-organisms, or watching closely the growth of micro-organisms, or some other interpretation.

Claim 12 recites the limitation "the final concentration" in step b). Claim 12 recites the limitation "the mixture" in steps e) and f). Claim 12 recites the limitation "the solution of hop acid" in step g). There are insufficient antecedent basis for these limitations in the claim. Applicant's claim is confusing and disjointed (see above regarding claim 2). Step c) of claim 12 recites the limitation "adding an alkaline medium to obtain a predefined pH". It is not clear to what compound an alkaline medium is being added. It is not clear as to what is meant by "mixture" recited in steps e) and f). It is not clear if the mixture of step e) is the same as the mixture of claim f). It is also not clear what is meant by term "raised temperature".

Claim 14 recites limitation "[a]n improved process for controlling the bacterial growth in a distillery comprising a yeast growing tank and a fermentor tank". It is not clear as to how process may comprise equipment. [REDACTED]

[REDACTED] It is not clear what is being added to the yeast and fermentor streams due to the

confusing claim language. It is not clear how recited "an effective antibacterial amount of an isomerized hop acid or derivative thereof" is related to the claim. Thus, it is not clear whether "an effective antibacterial amount of an isomerized hop acid or derivative thereof" is being added "to the yeast and fermentor streams" or there is other interpretation.

Claim 16 is indefinite for the recitation of the phrase "after dilution as an aqueous solution". There is insufficient antecedent basis for this limitation in the claim 14 from which claim 16 depends. Claim 14 does not set forth any dilution step as well as aqueous solution.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-6, 8-11, 14-15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975).

Todd, Jr. et al. disclose synthesis of hydrogenated purified beta acid (hexahydrolupulon) and its use as a selective inhibitor of cell growth (Col. 2 lines 33-41, Col. 3 lines 7-20). In regard to claim 2, Todd, Jr. et al. disclose “[a] process for producing hexahydrolupulone which comprises of the steps of contacting beta acids in an alkaline solution with a metal oxide, hydroxide, or salt” (Col. 2 lines 33-36). In regard to claims 2 and 14, Todd, Jr. et al. disclose “the addition of hexahydrolupulone to a yeast culture to inhibit the growth of Lactobacillus therein” (Col. 3 lines 7-8). In regard to claims 2 and 14, Todd, Jr. et al. disclose “the inhibition of a Lactobacillus microorganism in the presence of yeast without inhibiting growth of the yeast by the application of a Lactobacillus-inhibiting amount of hexahydrolupulone thereto” (Col. 3 lines 9-11). In regard to claims 2 and 14, Todd, Jr. et al. disclose “the selective inhibition of one microorganism in the presence of another by the application of an amount of hexahydrolupulone which is inhibitory as to the one microorganism but not the other” (Col. 3 lines 16-19). In regard to claim 3, Todd, Jr. et al. disclose 0.2% solution of hexahydrolupulone (Example 6). In regard to claims 5, 6 and 15 Todd, Jr. et al. disclose hexahydrolupulone (hexahydrobeta acid) (Example 4). In regard to claim 8, Todd, Jr. et al. disclose that “[t]he resulting pure hexahydrolupulone is useful as a growth inhibitor in such forms as a stable alkaline solution in water” (Col. 3 lines 40-43).

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In regard to claim 8, Todd, Jr. et al. discloses using KOH or NaOH and adjusting pH to 10 during hexahydrolupulone synthesis (Example 5). Todd, Jr. et al. disclose that:

Similar treatment of a 10% sugar solution, inoculated with yeast, did not inhibit fermentation. Accordingly, it is evident that the hexahydrolupulone solution may be used to selectively inhibit growth of specific cell lines, for example, the selective inhibition of Lactobacillus in the presence of yeast. Moreover, its use in inhibiting Lactobacillus infections in the brewhouse will become immediately apparent to one skilled in the brewing art. Other useful applications in fermentation processes, as well as pharmaceutical applications, will also be apparent to one skilled in the art.

(88) Although the hexahydrolupulone may be used as a neutral solution in alcohol or the like, its preferred form is as a stable alkaline solution as described in Example 5.

In regard to claim 9 and 20-21, Todd, Jr. et al. disclose that inhibition process was varied out at 20 degrees C (Example 6). In regard to claim 10, Todd, Jr. et al. disclose 0.2% solution of hexahydrolupulone to provide 50 ppm in the culture (Example 6).

Todd, Jr. et al. do not disclose that pH of the aqueous alkaline hop acid solution is higher than the pH of the aqueous process medium, the aqueous alkaline hop acid solution contains from about 2 to about 40 wt. % of hop acid, the aqueous process medium is a process medium in a yeast production process.

Since Todd, Jr. et al disclose that “[t]he resulting pure hexahydrolupulone is useful as a growth inhibitor in such forms as a stable alkaline solution in water”, alkaline solution would inherently have high pH value due to the presence of hydroxide ions in the solution. Since Todd, Jr. et al. disclose lower concentration of hexahydrolupulone than recited and the fact that disclosed hexahydrolupulone was highly purified, it would have been obvious to vary concentration of hop acid in a hop acid alkaline solution depending on the level of acid purity. Since Todd, Jr. et al teach selective inhibition of

one microorganism (bacilli generally and other bacteria) in the presence of yeast by the application of an amount of hexahydrolupulone which is inhibitory as to the one microorganism but not the yeast, it would have been obvious to employ the process as disclosed by Todd Jr. et al. in the yeast production process in order to inhibit the growth of all unwanted cells except for yeast as taught by Todd, Jr. et al.

Claims 7 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of Simpson (Synergism Between Hop Resins and Phosphoric Acid And Its Relevance To The Acid Washing of Yeast).

Kaneda et al (Beer Absorption on a Lipid Membrane as Related to Sen Evaluation) cited as evidence as discussed below.

Todd, Jr. et al. is taken as cited above.

Todd, Jr. et al. do not disclose isomerized hop acid.

Simpson discloses that hop acids present in the brewery yeast slurries have a bacterial action on lactic acid bacteria during the acid washing process (p. 405). Simpson disclose introduction into microorganisms of aqueous solution of "isomerised hop extract (ISOHOPCO2N, Pauls Hop Products, England) hopped to a level of 60° EBCBU" (p. 406). Simpson also discloses that solution contains 0-85% NaCl (p. 406). Thus Simpson discloses alkaline aqueous solution of isomerized hop acid. Simpson also discloses that alkaline aqueous solution of isomerized hop acid is maintained at 5° C (p. 406). As evidenced by Kaneda et al (Beer Absorption on a Lipid Membrane as

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Related to Sen Evaluation), the concentration of isomerized acids in ISOHOPCO2N product is 30%, in particular the concentration of isohumulone (isoalpha acid) is 21.6%.

Since Todd Jr. et al disclose aqueous hop acid alkaline solution as a selective inhibitor of cell growth, and Simpson discloses that hop acids have a bacterial action on lactic acid bacteria and adding aqueous isoalpha acid alkaline solution to yeast, it would have been obvious to modify disclosure of Todd et al and substitute synthesized hexahydrolupulone with commercially available aqueous isoalpha hop acid alkaline solution (ISOHOPCO2N) as a cell growth inhibitor in order to simplify the process and avoid multiple steps of hexahydrolupulone synthesis.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of Simpson (Synergism Between Hop Resins and Phosphoric Acid And Its Relevance To The Acid Washing of Yeast) and further in view of Todd, Jr. (US 4,002,863) hereinafter '863 Patent.

Todd, Jr. et al. and Simpson are taken as cited above.

In regard to claim 12, Simpson discloses isoalpha acid extract. In regard to claim 13, Simpson discloses that alkaline aqueous solution of isomerized hop acid is maintained at 5° C (p. 406).

Todd, Jr. et al. and Simpson do not disclose steps of aqueous alkaline hop acid solution preparation as recited.

'863 patent discloses a process for isomerizing alpha acids to iso-alpha acids. '863 patent discloses "a process for transforming an alpha acid into an iso-alpha acid, involving contact of the alpha acid with an aqueous solution of a metal ion, comprising

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the steps of contacting an aqueous solution of the metal ion with a water-immiscible organic solvent solution of the alpha acid under conditions where the alpha acid is dissolved or remains dissolved in said organic solvent and effecting the desired isomerization in the water-immiscible organic solvent with or without prior separation of said solvent containing said alpha acid from the aqueous phase, having numerous advantages over the prior art as herein elsewhere set forth" (Col. 4 lines 10-22). '863 patent discloses "the pH of any water phase is above 8.0 and preferably 13 or below and the temperature is below 50°C" (Col. 4 lines 31-33). '863 patent discloses "metal ions are introduced into the said hop extract while the solvent is present, the mixture held until isomerization occurs, and the solvent removed; metal ions are removed by washing the said hop extract contained in the solvent with dilute acid prior to removal of the solvent; the said mixture is held at a temperature below 50°C until isomerization occurs" (Col. 4 lines 40-47). '863 patent teaches the following advantages of the disclosed method: it eliminates the need to remove the solvent from the extract prior to isomerization; it permits continuous processing of the hops, from extraction to isomerization to solvent removal, without intermediate heating and cooling of the solvent; it permits the isomerization to be conducted at an increased rate, under conditions which eliminate the hazard of oxidation, hydrolysis, and further isomerization of the iso-alpha acids; it eliminates the necessity for carefully controlled amounts of reagents which, combined with mild conditions, makes the reaction foolproof; it greatly reduces the size and volume of equipment required to process a given quantity of hops,

because the concentration of extract in the water-immiscible solvent is not critical, and may in the process of this invention be very high (Col. 10 lines 50-68).

Since Simpson discloses that hop acids have a bacterial action on lactic acid bacteria and adding aqueous isoalpha acid alkaline solution to yeast, and '863 Patent teaches a process for isomerizing alpha acids to iso-alpha acids, it would have been obvious to modify combined teachings of Todd, Jr. et al. and Simpson and employ a method of preparation of aqueous alkaline hop acid solution in order to obtain aqueous isoalpha acid alkaline solution with all the commercial advantages listed above as taught by '863 Patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Stulii whose telephone number is (571) 272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VS
J. Stulz

K. Hendricks
KEITH HENDRICKS
PRIMARY EXAMINER